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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,417	05/04/2001	Ib Mendel-Hartvig	1614-0248P	7800

2292 7590 01/29/2004

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,417	MENDEL-HARTVIG ET AL.	
	Examin r	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with th corr spondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague with respect to the placement of the time indicator (14). The time indicator is recited to be arranged at a variable position between the upstream and downstream ends of the wicking member thereby permitting variation of the time elapsing from the application of the liquid until the indicator substance changes color; however, it is unclear how the elapsed time is measured. For example, if the time indicator is placed at location X, a predetermined distance from the sample application area, does it means that anything applied to the application area will take Y amount of time to migrate thereto? If so, this phenomenon needs to be clearly recited.

Claims 3, 4, 7 and 8 are vague and indefinite because they recite method steps or fabricating processes. Such method steps do not make clear the device of claim 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al (US 5,602,040).

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier. The device contains a labeled specific binding reagent for an analyte. The

labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material. (Column 2, lines 3-20). May teaches an embodiment where the device contains a control zone loaded with an antibody that will bind to the labeled antibody from the first zone; or the control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation. (Column 5, lines 8-27) May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (column 3, lines 22-32). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (column 9, lines 19-30). Quantitative measurement may be done visually by eye or by instrument. May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (column 7, lines 15-20). May also teaches an absorbant sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (column 5, line 58 through column 6, line 6). May teaches that the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction times during which the binding reaction can occur. Controls over these parameters can be achieved by the incorporation of viscosity modifiers such as sugars and modified celluloses to slow down the reagent migration (column 7, lines 30-39).

4. Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiser et al (EP 826,777).

Kiser discloses a chemical timer in a test strip for measuring the concentration of an analyte in a biological fluid. The test strip measures a predetermined interval chemically and comprises a dry coating of a colored indicator composition, a reagent that, when hydrated, is capable of reacting with glucose to change the color of the indicator, an inhibitor to inhibit the change in color of the indicator, and glucose, in which the inhibitor and glucose concentrations

in the dry coating are selected so that the glucose, over a predetermined time after the biological fluid sample is applied to the strip, reacts with the reagent to change the color of the indicator. When a sample is applied to the strip, hydration of the timer segment composition permits the color-forming reaction to proceed. The time it takes for the timer segment to change color is determined by the temperature and by characteristics of the testing reagent, specifically the inhibitor concentration, the amount of glucose, and the hydration and oxygen diffusion rates. The timer also serves as a quality control function, by making it apparent when a test strip has been contaminated by exposure to moisture. Migration of indicators having such a tendency may be prevented by including an ion pairing agent in the matrix.

5. Claims 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over May et al (US 5,602,040).

May differs from the instant invention in failing to specifically teach that the time indicator substance is applied to wicking member or to a support with is applied to the wicking member. However, May specifically teaches that the absorbant sink (i.e. wicking member) is either chromatography paper applied to the porous solid phase, or a length of porous solid phase material that extends beyond the detection zone (column 6, lines 1-6). May also teaches that the control zone (i.e. time indicator) is located downstream from the detection zone (column 5, lines 8-26), therefore, it can clearly be seen that the time indicator taught by May is located directly on the wicking member, or as an alternative, it is located on the wicking member and the wicking member is disposed on the test strip.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,785,978
US 6,046,058

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

22 January 2004